



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0280]

Agency Information Collection Activities; Proposed Collection; Comment Request;

Financial Disclosure by Clinical Investigators

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collections regarding financial disclosure by clinical investigators.

DATES: Submit either electronic or written comments on the collection of information by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of **[INSERT DATE 60 DAYS AFTER DATE OF**

PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2012-N-0280 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Financial Disclosure by Clinical Investigators.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about

FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper

performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Financial Disclosure by Clinical Investigators--21 CFR Part 54

OMB Control Number 0910-0396--Extension

Respondents to this collection are sponsors of marketing applications that contain clinical data from studies covered by the applicable regulations. These sponsors represent pharmaceutical, biologic, and medical device firms. Respondents are also clinical investigators who provide financial information to the sponsors of marketing applications.

Table 1 shows information that is the basis of the estimated number of respondents in tables 2 through 4.

Table 1.--Estimated Number of Applications, Clinical Trials, and Investigators Subject to the Regulation by Type of Application¹

Application Type	Total No. of Applications	No. of Applications Affected	No. of Trials	No. of Investigators
Drugs:				
New drug application (NDA), new molecular entity (NME)	35	26	3 to 10	3 to 100
NDA non-NME				
NDA efficacy supplement	173	86	1 to 3	10 to 30
Abbreviated new drug application (ANDA)	1,152	250	1.1	2
ANDA supplement	6,774	383	1	2
Biologics:				
Biologics license application (BLA)	22	19	3 to 10	3 to 100
BLA efficacy supplement	16	14	1 to 3	10 to 30
Medical Devices:				
Premarket approval (PMA)	48	48	1 to 3	10 to 20
PMA supplement	23	23	1 to 3	3 to 10
Reclassification devices	3	1	1	3 to 10
510(k)	4,000	200	1	3 to 10

¹ Source: Agency estimates

FDA estimates the burden of this collection of information as follows:

Reporting Burden:

Under § 54.4(a) (21 CFR 54.4(a)), applicants submitting an application that relies on clinical studies must submit a complete list of clinical investigators who participated in a covered clinical study, and must either certify to the absence of certain financial arrangements with clinical investigators (Form FDA 3454) or, under § 54.4(a)(3), disclose to FDA the nature of those arrangements and the steps taken by the applicant or sponsor to minimize the potential for bias (Form FDA 3455).

FDA estimates that almost all applicants submit a certification statement under § 54.4(a)(1) and (2). Preparation of the statement using Form FDA 3454 should require no more than 1 hour per study. The number of respondents is based on the estimated number of affected applications.

When certification is not possible, and disclosure is made using Form FDA 3455, the applicant must describe, under § 54.4(a)(3), the financial arrangements or interests and the steps that were taken to minimize the potential for bias in the affected study. As the applicant would be fully aware of those arrangements and the steps taken to address them, describing them will be straightforward. The Agency estimates that it will take about 5 hours to prepare this narrative. Based on our experience with this collection, FDA estimates that approximately 10 percent of the respondents with affected applications will submit disclosure statements.

Table 2.--Estimated Annual Reporting Burden¹

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Certification--54.4(a)(1) and (2)--Form FDA 3454	1,050	1	1,050	1	1,050
Disclosure--54.4(a)(3)--Form FDA 3455	105	1	105	5	525
Total					1,575

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Recordkeeping Burden:

Under § 54.6, the sponsors of covered studies must maintain complete records of compensation agreements with any compensation paid to nonemployee clinical investigators, including information showing any financial interests held by the clinical investigator, for 2 years after the date of approval of the applications. Sponsors of covered studies maintain many records regarding clinical investigators, including protocol agreements and investigator résumés or curriculum vitae. FDA estimates that an average of 15 minutes will be required for each recordkeeper to add this record to the clinical investigators' file.

Table 3.--Estimated Annual Recordkeeping Burden¹

21 CFR Section	No of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours ²
Recordkeeping--54.6	1,050	1	1,050	0.25 (15 minutes)	263

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² Numbers have been rounded.

Third-Party Disclosure Burden:

Under § 54.4(b), clinical investigators supply to the sponsor of a covered study financial information sufficient to allow the sponsor to submit complete and accurate certification or disclosure statements. Clinical investigators are accustomed to supplying such information when applying for research grants. Also, most people know the financial holdings of their immediate

family and records of such interests are generally accessible because they are needed for preparing tax records. For these reasons, FDA estimates that the time required for this task may range from 5 to 15 minutes; we used the mean, 10 minutes, for the average burden per disclosure. The number of respondents is the sum of the number of affected applications multiplied by the mean (rounded) of the estimated number of investigators for each application type (see table 1).

Table 4.--Estimated Annual Third-Party Disclosure Burden¹

21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours ²
54.4(b)--Clinical Investigators	7,894	1	7,894	0.17 (10 minutes)	1,342

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² Numbers have been rounded.

Our estimated burden for the information collection reflects an overall increase of 222 hours and a corresponding increase of 893 responses/records. We attribute this adjustment to an increase in the number of affected applications and the number of investigators. No program changes were made.

Dated: September 21, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-21039 Filed: 9/26/2018 8:45 am; Publication Date: 9/27/2018]